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FIRST NAMED INVENTOR APPLICATION NO. FILING DATE ATTORNEY DOCKET NO. CONFIRMATION NO. 10/079,693 02/20/2002 Nikolai M. Krivitski 86017.000025 7395 23387 7590 09/27/2004 **EXAMINER** Stephen B. Salai, Esq. NASSER, ROBERT L Harter, Secrest & Emery LLP ART UNIT PAPER NUMBER 1600 Bausch & Lomb Place Rochester, NY 14604-2711 3736

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)	
Office Action Summary		10/079,693	KRIVITSKI ET AL.	
		Examiner	Art Unit	
		Robert L. Nasser	3736	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).				
Status				
1)□ F	Responsive to communication(s) filed on	<u>.</u> .		
2a) <u> </u>	This action is FINAL . 2b)⊠ This	action is non-final.		
-	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is			
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.				
Disposition of Claims				
4)⊠ Claim(s) <u>1-29</u> is/are pending in the application.				
4:	4a) Of the above claim(s) 4-9,13,15 and 20-25 is/are withdrawn from consideration.			
5)⊠ C	5)⊠ Claim(s) <u>18 and 19</u> is/are allowed.			
6)⊠ (S)⊠ Claim(s) <u>1,10,11,16 and 17</u> is/are rejected.			
,	7)⊠ Claim(s) <u>2,3,12 and 26-29</u> is/are objected to.			
8) Claim(s) are subject to restriction and/or election requirement.				
Application Papers				
9) The specification is objected to by the Examiner.				
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).				
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.				
Priority under 35 U.S.C. § 119				
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received.				
Certified copies of the priority documents have been received in Application No				
3. Copies of the certified copies of the priority documents have been received in this National Stage				
application from the International Bureau (PCT Rule 17.2(a)).				
* See the attached detailed Office action for a list of the certified copies not received.				
Attachment(s)				
	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail Da		
3) 🗵 Informa	ation Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	5) 🔲 Notice of Informal P	atent Application (PTO-152)	
Paper No(s)/Mail Date <u>7/19/2002</u> . 6) Uther:				

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This application contains claims directed to the following patentably distinct species of the claimed invention:

Species I, drawn to number 1. on page 24, line 13, pre calibration. .

Species II, drawn to number 2. on page 24, line 16, a plurality of injections

. .

Species III, drawn to number 3.onpage 24, line 19, a plurality of thermal sensors. . .

Species IV, drawn to number 4 on page 24, line 22, a plurality of precalibrated . . .

Species V, drawn to number 5. on page 24, line 25, creating special construction . . .

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 11, and 17 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by

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37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Mr. Brian Shaw on September 13, 2004 a provisional election was made with traverse to prosecute the invention of species I, claims 1-3, 11, 12, 14, 17, 18, 19, and 26-29. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4-9, 13, 15, and 20-25 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. The examiner notes that the search uncovered art related to species V and so the examiner has included species V, claims 10 and 16 in the elected embodiments.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

⁽b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 10, 11, 16, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolzinger et al 5,271,410. Wolzinger thermally isolates the thermistor from the lumen that carries injectate to offset for variations caused by the injectate passing near the thermistor (see last four lines of the abstract and column 3, lines 3-14).

Claims 2, 3, 12, 14, and 26-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 18 and 19 are allowable.

Claims 2, 3, 12, 14, 18, 19, and 26-29 define over the art in that none of the art compensates for inside cooling by either precalibrating the thermally conductive properties of the catheter or by determining a calibration coefficient or thermal transfer coefficient for the catheter and adjusting a thermodilution measurement using the coefficient.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Quinn et al and Svanerudh et al both identify inside cooling as a source of error in thermodilution measurements.

Khalil corrects for inside heating in a heating thermodilution system.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on Mon-Fri, variable hours.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser Primary Examiner Art Unit 3736

RLN September 20, 2004

> ROBERT L. NASSER PRIMARY EXAMINER

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